



PATENT APPLICATION

IN THE U.S. PATENT AND TRADEMARK OFFICE

June 7, 2007

Applicant(s): Joachim KOERNER, et al

For: MICRODOSING DEVICE

Serial No.: 10/777 257 Group: 3772

Confirmation No.: 5395

Filed: February 12, 2004 Examiner: Patel

International Application No.: N/A

International Filing Date: N/A

Atty. Docket No.: Ruff 19

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF**

Sir:

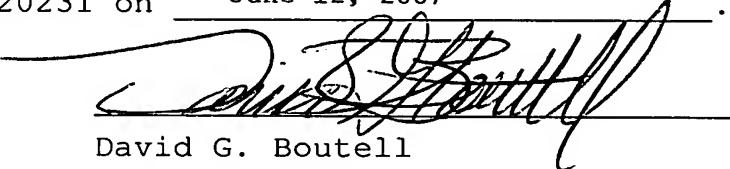
In response to the Notification of Non-Complaint Appeal Brief dated May 29, 2007, enclosed herewith is a Supplemental Appeal Brief in which the "STATUS OF CLAIMS" has been amended.

(Please see following pages.)

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CERTIFICATE OF MAILING

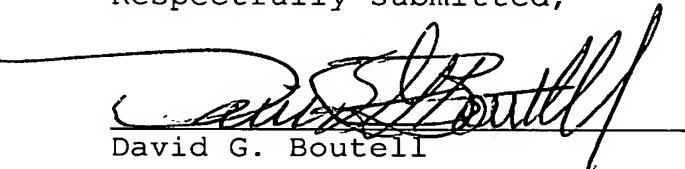
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on June 12, 2007.

  
David G. Boutell

REMARKS

In response to the Notification dated May 29, 2007, Applicants are enclosing herewith a Supplemental Appeal Brief which points out that Claims 10-19 are pending in the application and are under appeal, and that Claims 1-9 are cancelled.

Respectfully submitted,

  
David G. Boutell

DGB/DJW/jas

FLYNN, THIEL, BOUTELL & TANIS, P.C. 2026 Rambling Road Kalamazoo, MI 49008-1631 Phone: (269) 381-1156 Fax: (269) 381-5465	Dale H. Thiel David G. Boutell Terryence F. Chapman Mark L. Maki Liane L. Churney Brian R. Tumm Steven R. Thiel Donald J. Wallace Sidney B. Williams, Jr.	Reg. No. 24 323 Reg. No. 25 072 Reg. No. 32 549 Reg. No. 36 589 Reg. No. 40 694 Reg. No. 36 328 Reg. No. 53 685 Reg. No. 43 977 Reg. No. 24 949
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Encl: Supplemental Appellant's Brief on Appeal  
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PATENT APPLICATION

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**SUPPLEMENTAL APPELLANT'S BRIEF ON APPEAL**

Sir:

This is an appeal from the final rejection dated May 16, 2006, finally rejecting Claims 10-19.

**REAL PARTIES IN INTEREST**

Ing. Erich Pfeiffer GmbH is the assignee of the present application and the real party in interest.

**RELATED APPEALS AND INTERFERENCES**

There are no related appeals and interferences with the present application.

**STATUS OF CLAIMS**

Claims 10-19 are pending in the present application and are under appeal. Claims 1-9 are cancelled. Claims 10, 12, 14 and 15 have been rejected by the Examiner under 35 USC §112, first paragraph, as failing to comply with the written

description requirement. Claims 10-19 have been rejected by the Examiner under 35 USC §102(b) as being anticipated by US Patent 6 196 219 to Hess et al.

STATUS OF AMENDMENTS

None.

SUMMARY OF CLAIMED SUBJECT MATTER

Appellants' invention, as defined by independent Claim 10, is directed to a method of operating a microdosing device. The microdosing device has a dosing chamber for reception of a liquid quantity, and at least one discharge opening is associated with the dosing chamber. A vibrating unit is in operative connection with at least one boundary surface of the dosing chamber in order to vibrate the same for a discharge process. A delivery function unit is connected to the vibrating unit for activating the latter during a delivery time period. The microdosing device also includes a drying function unit. The method includes the steps of activating the vibrating unit during a delivery time period, pausing for a pre-determined time separation period, and activating the drying function unit to remove liquid residues from the dosing chamber (Figures 1-3 and Specification page 2, line 1 through Specification page 8, line 9).

Appellants' invention, as defined by independent claim 12, is directed to a method of operating a microdosing device. The microdosing device has a dosing chamber for reception of a liquid quantity, and at least one discharge opening is associated with the dosing chamber. A vibrating unit is in operative connection with at least one boundary surface of the dosing chamber in order to vibrate the same for a discharge process. A delivery function unit is connected to the vibrating unit for activating the latter during a delivery time period. The microdosing device also includes a drying function unit, for removing liquid residues from the dosing chamber, which is configured for activation in time-separated

manner with respect to the delivery function unit. The delivery function unit and drying function unit are parts of a common electronic control device provided with a time function element for coordinating the time-separated activating processes of the delivery function unit and the drying function unit. The method includes the steps of activating the delivery function unit to dispense a medium, activating the time delay unit for a pre-determined time-separation, and activating the drying function unit for a drying process (Figures 1-3 and Specification page 2, line 1 through Specification page 8, line 9).

Appellants' invention, as defined by independent claim 14, is directed to a method for dosing small liquid quantities by the vibration of at least one boundary surface of a dosing chamber by activating and deactivating a vibrating unit. The method includes the steps of activating the vibrating unit for a delivery time period for the discharge of the liquid quantity, deactivating the vibrating unit and initiating a time delay, and initiating a drying process to remove liquid residues remaining in the dosing chamber (Figures 1-3 and Specification page 2, line 1 through Specification page 8, line 9).

#### GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants wish the Board of Appeal to review the rejection of Claims 10, 12, 14 and 15 as failing to comply with the written description requirement under 35 USC §112, first paragraph, and to review the rejection of Claims 10-19 under 35 USC §102(b) as being anticipated by US Patent 6 196 219 to Hess et al.

#### ARGUMENT

The presently claimed invention is directed to a microdosing device having a dosing chamber, with which is associated at least one discharge opening, and a vibrating unit in operative connection with at least one boundary

surface of the dosing chamber in order to vibrate the dosing chamber for a discharge process. A delivery function unit is connected to the vibrating unit for activating the vibrating unit during a delivery time period. A drying function unit is activated in time-separated manner from the delivery function unit in order to free the dosing chamber from liquid residues. As a result of the time separation of the delivery function and the drying function, a clearly time-defined dosability of the corresponding liquid is ensured. As a result, it is possible to keep the dosing volume the same based on the precise time interval of the delivery function. There is no lagging of the vibrating unit beyond the delivery time. In a pharmaceutical application, the drying function is performed in time-displaced manner with respect to the delivery period, so that any liquid residues which have passed to the outside during the drying process no longer enter the human body and are instead given off to the environment. Preferably, the vibrating unit operates with ultrasonic waves, in that a piezoelectric actuator is excited with a corresponding frequency. The vibrating unit can also have actuators, which operate with different excitation vibrations or waves.

U.S. Patent 6 196 219 to Hess et al. discloses a liquid droplet spray device for an inhaler that comprises a microdosing device with a dosing chamber for receiving a liquid quantity and with which is associated a discharge opening. The microdosing device includes a vibrating unit in operative connection with at least one boundary surface of the dosing chamber. The vibrating unit is disclosed as a piezoelectric element that is controllable for activation during the duration of an atomization cycle. The microdosing unit is also disclosed as including a flexible heating surface for heating the liquid to a predetermined temperature that is advantageous for dispersal. The heating element is also disclosed as being capable of contributing, at the end of the atomization cycle, to the evaporation of any liquid left in the dosing chamber, and that the vibrating unit may continue

operation for a predetermined time after the inhalation cycle has ended.

Rejections under 35 USC §112

-Claim 10

According to Claim 10, a method of operating a microdosing device having a dosing chamber for the at least partial reception of a liquid quantity and with which is associated at least one discharge opening, a vibrating unit in operative connection with at least one boundary surface of the dosing chamber in order to vibrate the same for a discharge process, a delivery function unit, connected to the vibrating unit, for activating the latter during a delivery time period, and a drying function unit, comprises the steps of activating the vibrating unit during a delivery time period; *pausing for a pre-determined time separation period*; and activating the drying function unit to remove liquid residues from the dosing chamber. [Emphasis added]

In the rejection of Claim 10 under 35 USC §112, first paragraph, the Examiner states that the subject matter "pausing for a pre-determined time separation period" was not described in the specification.

This subject matter from Claim 10 is found in several locations in the specification and drawings. At paragraph [005], lines 1-5, it states "This problem is solved in that additionally a drying function unit is provided, which is activatable in time-separated manner from the delivery function in order to free the dosing chamber from liquid residues. As a result of the time separation of the delivery function and the drying function a clearly time-defined dosability of the corresponding liquid is ensured." At paragraph [005], lines 12-13: "According to the invention, the drying function is performed in time-displaced manner with respect to the application period..." In paragraph [008], lines 8-10, "The time function element ensures the time separation between the delivery function and the drying function."

Referring to Figure 2, paragraph [020], lines 42-43 of the specification, "As from the time  $t_2$  and up to a time  $t_3$  the piezoelectric actuator 6 is switched off, i.e. deactivated," and the final three lines of paragraph [020] refer to a subsequent application, i.e., "Now a further dosing process can take place, which once again leads in time-separated manner to a corresponding drying process."

Appellants argue that these recitations in the specification and drawings describe the claimed method step in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In light of these recitations in the disclosure, reversal of the Examiner's rejection of Claim 10 under 35 USC §112, first paragraph, is respectfully solicited.

-Claim 12

According to Claim 12, a method of operating a microdosing device having a dosing chamber for the at least partial reception of a liquid quantity and with which is associated at least one discharge opening, a vibrating unit in operative connection with at least one boundary surface of the dosing chamber in order to vibrate the same for a discharge process, a delivery function unit, connected to the vibrating unit, for activating the latter during a delivery time period, and a drying function unit for removing liquid residues from the dosing chamber, configured for activation in time-separated manner with respect to the delivery function unit, wherein the delivery function unit and drying function unit are parts of a common electronic control device provided with a time function element for coordinating the time-separated activating processes of the delivery function unit and the drying function unit, comprises the steps of activating the delivery function unit to dispense a medium; activating the time delay unit for a pre-determined time-separation; and

activating the drying function unit for a drying process. [Emphasis added]

In the rejection of Claim 12 under 35 USC §112, first paragraph, the Examiner states that the subject matter "activating the time delay unit for a pre-determined time-separation" was not described in the specification.

This subject matter from Claim 12 is found in several locations in the specification and drawings. At paragraph [005], lines 1-5, it states "This problem is solved in that additionally a drying function unit is provided, which is activatable in time-separated manner from the delivery function in order to free the dosing chamber from liquid residues. As a result of the time separation of the delivery function and the drying function a clearly time-defined dosability of the corresponding liquid is ensured." At paragraph [005], lines 12-13: "According to the invention, the drying function is performed in time-displaced manner with respect to the application period..." In paragraph [008], lines 8-10, "The time function element ensures the time separation between the delivery function and the drying function." Referring to Figure 2, paragraph [020], lines 42-43 of the specification, "As from the time  $t_2$  and up to a time  $t_3$  the piezoelectric actuator 6 is switched off, i.e. deactivated," and the final three lines of paragraph [020] refer to a subsequent application, i.e., "Now a further dosing process can take place, which once again leads in time-separated manner to a corresponding drying process."

Appellants argue that these recitations in the specification and drawings describe the claimed method step in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In light of these recitations in the disclosure, reversal of the Examiner's rejection of Claim 12 under 35 USC §112, first paragraph, is respectfully solicited.

-Claim 14

According to Claim 14, a method for dosing small liquid quantities, by the vibration of at least one boundary surface of a dosing chamber by activating and deactivating a vibrating unit, comprises the steps of activating the vibrating unit for a delivery time period for the discharge of the liquid quantity, *deactivating the vibrating unit and initiating a time delay*; and initiating a drying process to remove liquid residues remaining in the dosing chamber. [Emphasis added]

In the rejection of Claim 14 under 35 USC §112, first paragraph, the Examiner states that the subject matter "deactivating the vibration [sic] unit and initiating a time delay" was not described in the specification.

This subject matter from Claim 14 is found in several locations in the specification and drawings. At paragraph [005], lines 1-5, it states "This problem is solved in that additionally a drying function unit is provided, which is activatable in time-separated manner from the delivery function in order to free the dosing chamber from liquid residues. As a result of the time separation of the delivery function and the drying function a clearly time-defined dosability of the corresponding liquid is ensured." At paragraph [005], lines 12-13: "According to the invention, the drying function is performed in time-displaced manner with respect to the application period..." In paragraph [008], lines 8-10, "The time function element ensures the time separation between the delivery function and the drying function." Referring to Figure 2, paragraph [020], lines 42-43 of the specification, "As from the time  $t_2$  and up to a time  $t_3$  the piezoelectric actuator 6 is switched off, i.e. deactivated," and the final three lines of paragraph [020] refer to a subsequent application, i.e., "Now a further dosing process can take place, which once again leads in time-separated manner to a corresponding drying process."

Appellants argue that these recitations in the specification and drawings describe the claimed method step in

such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In light of these recitations in the disclosure, reversal of the Examiner's rejection of Claim 14 under 35 USC §112, first paragraph, is respectfully solicited.

-Claim 15

According to Claim 15, in the method of claim 14, the drying process further comprises activating the vibrating unit over a drying time period.

In the rejection of Claim 15 under 35 USC §112, first paragraph, the Examiner states that the subject matter "activating the vibrating unit over a drying time period" was not described in the specification.

This subject matter from Claim 15 is found in the specification, referring to Figure 2, at paragraph [020], lines 47-55, "...from time  $t_3$  the piezoelectric actuator 6 is activated, i.e. switched on by the drying function unit 11. As the base structure 4 and membrane 2 substantially dry vibrate due to the activation of the piezoelectric actuator 5, the dosing chamber 3 is subject to heating, so that any liquid residues present evaporate and are discharged through the discharge openings 5. The drying function unit 11 activates the piezoelectric actuator 5 up to the time  $t_4$  and then switches it off, i.e. deactivates it."

Appellants argue that this recitation in the specification and drawings describe the claimed method step in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In light of this recitation in the disclosure, reversal of the Examiner's rejection of Claim 15 under 35 USC §112, first paragraph, is respectfully solicited.

Rejections under 35 USC §102

In the rejection under 35 USC §102(b), the Examiner has stated that:

Hess discloses a liquid droplet spray device for an inhaler suitable for respiratory therapies that comprises a micro-dosing device 5 having a dosing chamber 9 for the at least partial reception of a liquid quantity and with which is associated at least one discharge opening 14, a vibrating unit 10 in operative connection with at least one boundary surface of the dosing chamber in order to vibrate the same for a discharge process, a delivery function unit, connected to the vibrating unit, for activating the latter during a delivery time period, and drying function unit, the method comprising the steps of activating the vibrating unit during a delivery time period; pausing for a pre-determined time separation period (**Inherently there is a pause between the inhalation period and the drying period**); and activating the drying function unit to remove liquid residues from the dosing chamber. [Emphasis in original]

-Claims 10-11

Appellants argue that Examiner's assertion that Hess et al. '219 discloses that "inherently there is a pause between the inhalation and the drying period" is incorrect. Hess et al. '219 does not teach any pause between the inhalation and drying cycles, and the existence of a pause cannot be inferred from the absence of any disclosure related to the switching from the inhalation to the drying cycles. However, even if a pause were believed to be inherent, such disclosure still does not reach the claimed invention. Hess et al. '219 does not teach a method of operation of the microdosing device including a step of pausing for a pre-determined time separation period between a delivery time period and activation of the drying function unit to remove liquid residues from the dosing chamber, as required by Claim 10.

In further support of the argument that Hess et al. '219 does not teach the concept of a pre-determined time separation, or a time delay, Hess et al. '219 discloses that the vibrating unit may continue after the inhalation cycle has been completed, in conjunction with the heating element. More

specifically, Hess et al. '219 advocates, at column 7, lines 18-22, the continuation of the actuation of the "vibrating means" after the inhalation cycle has ended, rather than any time delay to separate the inhalation and drying cycles. This arrangement has the disadvantage that any residue remaining in the dosing chamber may be introduced into the inhalation cycle, resulting in imprecise dosing by the microdosing device.

The microdosing device according to the claimed invention is specifically directed to overcome this failing of the prior art by providing a distinct, time-separated drying of the dosing chamber. By providing a time-separated drying time for removing residue from the dosing chamber, the microdosing device ensures a more precise dosing, in that the user, for example, is no longer inhaling during the drying time. Further, the time-separated drying period still ensures that residue is eliminated before a subsequent delivery/inhalation cycle is initiated. These advantages are not realized, or anticipated, by the teaching of Hess et al. '219.

Claim 11 depends from Claim 10. For the reasons cited above, the subject matter of Claim 11 is further not disclosed by Hess et al. '219.

-Claims 12-13

Appellants argue that Examiner's assertion that Hess et al. '219 discloses that "inherently there is a pause between the inhalation and the drying period" is incorrect. Hess et al. '219 does not disclose a method of operating a microdosing device comprising the step of activating the time delay unit for a pre-determined time-separation, as required by Claim 12. The argument presented above with respect to Claim 10 is further incorporated herein.

Claim 13 depends from Claim 12. For the reasons cited above, the subject matter of Claim 13 is further not disclosed by Hess et al. '219.

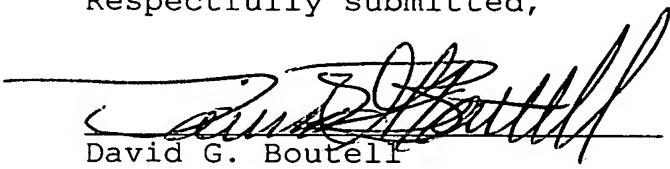
-Claims 14-19

Appellants argue that Examiner's assertion that Hess et al. '219 discloses that "inherently there is a pause between the inhalation and the drying period" is incorrect. Hess et al. '219 does not disclose the method for dosing small liquid quantities comprising the step of deactivating the vibrating unit and initiating a time delay, as required by Claim 14. The argument present above with respect to Claim 10 is further incorporated herein.

Claims 15-19 depend from Claim 14. For the reasons cited above, the subject matter of Claims 15-19 is further not disclosed by Hess et al. '219.

Reversal of the Examiner's rejection of Claims 10-19 is respectfully solicited.

Respectfully submitted,

  
\_\_\_\_\_  
David G. Boutell

DGB/DJW/jas

FLYNN, THIEL, BOUTELL & TANIS, P.C. 2026 Rambling Road Kalamazoo, MI 49008-1631 Phone: (269) 381-1156 Fax: (269) 381-5465	Dale H. Thiel David G. Boutell Terryence F. Chapman Mark L. Maki Liane L. Churney Brian R. Tumm Steven R. Thiel Donald J. Wallace Sidney B. Williams, Jr.	Reg. No. 24 323 Reg. No. 25 072 Reg. No. 32 549 Reg. No. 36 589 Reg. No. 40 694 Reg. No. 36 328 Reg. No. 53 685 Reg. No. 43 977 Reg. No. 24 949
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Encl:      Claims Appendix  
                Evidence Appendix  
                Related Proceedings Appendix

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Claims Appendix

1-9. (Cancelled)

10. A method of operating a microdosing device having a dosing chamber for the at least partial reception of a liquid quantity and with which is associated at least one discharge opening, a vibrating unit in operative connection with at least one boundary surface of the dosing chamber in order to vibrate the same for a discharge process, a delivery function unit, connected to the vibrating unit, for activating the latter during a delivery time period, and a drying function unit, the method comprising the steps of:

activating the vibrating unit during a delivery time period;

pausing for a pre-determined time separation period; and

activating the drying function unit to remove liquid residues from the dosing chamber.

11. The method according to Claim 10, wherein the delivery function unit and drying function unit are parts of a common electronic control.

12. A method of operating a microdosing device having a dosing chamber for the at least partial reception of a liquid quantity and with which is associated at least one discharge opening, a vibrating unit in operative connection with at least one boundary surface of the dosing chamber in order to vibrate the same for a discharge process, a delivery function unit, connected to the vibrating unit, for activating the latter during a delivery time period, and a drying function unit for removing liquid residues from the dosing chamber, configured for activation in time-separated manner with

respect to the delivery function unit, wherein the delivery function unit and drying function unit are parts of a common electronic control device provided with a time function element for coordinating the time-separated activating processes of the delivery function unit and the drying function unit, the method comprising the steps of:

activating the delivery function unit to dispense a medium;

activating the time delay unit for a pre-determined time-separation; and

activating the drying function unit for a drying process.

13. The method according to Claim 12, wherein the drying function unit is connected to the vibrating unit and further comprising the step of activating the vibrating unit for the drying process.

14. A method for dosing small liquid quantities by the vibration of at least one boundary surface of a dosing chamber by activating and deactivating a vibrating unit, comprising the steps of:

activating the vibrating unit for a delivery time period for the discharge of the liquid quantity,

deactivating the vibrating unit and initiating a time delay; and

initiating a drying process to remove liquid residues remaining in the dosing chamber.

15. The method according to claim 14, wherein the drying process further comprises activating the vibrating unit over a drying time period.

16. The method according to claim 15, wherein the drying process further comprises the step of activating a heating device affecting the dosing chamber.

17. The method according to claim 16, wherein the drying process further comprises the step of activating a delivery device for pumping out the liquid residues.

18. The method according to claim 14, wherein the drying process further comprises the step of activating a heating device affecting the dosing chamber.

19. The method according to claim 14, wherein the drying process further comprises the step of activating a delivery device for pumping out the liquid residues.

EVIDENCE APPENDIX

There is no evidence.

RELATED PROCEEDINGS INDEX

There are no related proceedings.